

NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled SPIRIT PHARMACEUTICALS LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

NIGHTTIME SLEEP-AID

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCL 50 mg

Purpose

Nighttime sleep-aid

Uses

- for relief of occasional sleeplessness

Warnings

Do not use

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

avoid alcoholic drinks

Stop use and ask a doctor if

sleeplessness persist continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional before use.

keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

1(800)222-1222

Directions

- adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Inactive ingredients

FD&C Blue#1, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol, titanium dioxide, water

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Maximum Strength

Nighttime Sleep-aid

Diphenhydramine HCl 50 mg - Nighttime Sleep-Aid

Helps reduce difficulty falling asleep

Non-habit forming

8 Softgels

VALUHEALTH

Compare to Unisom®
SleepGels®
active ingredient†

Maximum Strength

nighttime sleep-aid

Diphenhydramine HCl 50 mg - Nighttime Sleep-Aid

Helps reduce difficulty falling asleep
Non-habit forming

Actual Size

8 softgels

NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4147
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	206;903
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4147-8	1 in 1 CARTON	04/28/2021	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	04/28/2021	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 11/2021

SPIRIT PHARMACEUTICALS LLC